

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2018153	<b>(X3) Date Survey Completed</b>  12/03/2021
<b>Name of Provider or Supplier</b>  Aqua Dermatology Of Alabama Pc	<b>Street Address, City, State</b>  1401 Edwards Lake Road, Birmingham, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Leica CM 1800 cryostat Operator's Manuals, a lack of room temperature and room humidity records, and an interview with the Histotechnician, the laboratory failed to monitor and document room temperature and humidity to ensure the Cryostat was operated within the environmental parameters specified by the manufacturer. The findings include: 1. A review of Leica CM 1800 cryostat Operator's Manual stated "Operating temperature range (ambient temperature): 18 degrees C to 40 degrees C. All specifications related to temperature are valid only up to an ambient temperature of 22 degrees C and an air humidity lower than 60%." 2. During an interview conducted on 12/03/2021 at 10:45 AM, the Histotechnician confirmed that the laboratory had not monitored and documented room temperature and humidity for this laboratory.</p>